

ELECTION BY APPLICANT.

Applicant provisionally elects SEQ ID NO: 1 for the polypeptide sequence from {1)-4)} and cortisone for the anti-inflammatory from {a)-u)}. The claims readable on this election include claims 1-4, 7-9, 10-13, 16-19, 20-23, 26-28, 29-32, 35-38.

REMARKS

1. Restriction among the Markush claims.

The claims that have been restricted in the Office Action consist of Markush type claims. Applicant respectfully submits the restrictions are improper.

i. Restriction among the polypeptide sequences

Claims 2, 11, 21 and 30 are Markush claims, listing the four polypeptides as members. Under MPEP § 803.02, if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, restriction will not be required. Moreover, it is improper to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention.

Broadly speaking, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. MPEP § 803.02. Restriction of the polypeptides is improper because they are sufficiently few in number (four), they share a common utility (anti-inflammatory activity), and they share a substantial structural feature disclosed as being

essential to that utility (amino acid sequences Lysine-Proline-Valine at the C-terminus of the peptide).

ii. Restriction among the anti-inflammatories

The Office Action asserts that the anti-inflammatories a)-u) (as listed in the Office Action) are patentably distinct. The Office Action does not explain the grounds upon which the members of the list have been determined to be patentably distinct and thus subject to restriction. Applicant believes the restriction requirement among anti-inflammatories to be in error and respectfully requests that it be withdrawn.

The claims here, as above, contain a unity of invention; claims 3 and 4 share common utility in that they are known in the art as anti-inflammatories and have a substantial structural feature in that they are all steroid based. Similarly, claims 5 and 6 share a common utility as anti-inflammatories and a substantial structural feature in that they are non-steroid based.

Claims 4 and 6 are also Markush type claims. As noted above, it is improper to restrict Markush-type claims if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden. MPEP § 803.02. In such a situation, restriction is not required, and all the members of the Markush group should be examined, even if the members are directed to independent and distinct inventions. *Id.* The originally filed dependent claims are divided between glucocorticoid anti-inflammatories and nonsteroidal anti-inflammatories. Claim 3 is generic to glucocorticoids; claim 4 (dependent on claim 3) is written in Markush format claiming glucocorticoids a)-j). Likewise, claim 5 is generic to non-steroidal anti-

inflammatory drugs; claim 6 (dependent on claim 5) is written in Markush format claiming non-steroidal anti-inflammatory drugs k)-u). Nonetheless, the restriction requirement combines the claims into one list (claim 4, containing 10 members, and claim 6, containing 11 members), containing 21 members.

Applicant respectfully submits that the Office Action creates an artificial Markushtype grouping out of separate Markush claims such that the resultant Markush group has an unreasonable number of members and members that may possibly require separate searching.

Applicant submits that creation of such a claim is improper and that the claims as written do no create an unreasonable number of members nor a burdensome search for the Examiner. Applicant requests this restriction be withdrawn. In the alternative, Applicant respectfully submits the following proposal to remedy.

iii. Proposal for re-identification of species

Applicant proposes that the claims should be restricted into two groups: Group I directed to glucocorticoid anti-inflammatories {a) beclomethasone diproprionate, b) betamethasone, c) cortisone, d) dexamethasone, e) fluconide, f) hydrocortisone, g) methylprednisolone, h) prednisolone, i) prednisone, j) triamcinolone}, in combination with a terminal KPV polypeptide, and Group II directed to non-steroidal anti-inflammatories {k) aspirin, l) diffusinal, m) fenoprophen calcium, n) ibuprofen, o) indomethicin, p) meclofenamate sodium, q) naproxen, r) phenylbutazone, s) piroxicam, t) sulindac, u) tolectin sodium} in combination with a terminal KPV polypeptide.

As the specification and claims recite, these groups are separated by nature of whether a compound can be classified as a glucocorticoid or a non-steroidal anti-inflammatory drug.

Thus, a proper grouping should include the glucocorticoids, of which each are a steroid based anti-inflammatory agent, and non-steroidal anti-inflammatory drugs, of which its members are non-steroid based.

2. Restriction among the polypeptides.

Applicant submits that restriction among the polypeptides is improper. The polypeptides are related in that each claimed peptide contains a C-terminus KPV. In order to justify restriction where the several inventions are related, the Examiner must show one of the following: 1) separate classification, 2) separate status in the art, or 3) different field of search. MPEP § 808.02. As noted in the Office Action, the polypeptides are drawn to the same class (424) and subclass (185.1). Concerning the second requirement, the Office Action does not demonstrate that each peptide enjoys separate status in the art. Finally the Office Action is silent regarding different fields of search.

As none of the criteria for restriction under MPEP § 808.02 are met, Applicant respectfully requests this restriction be withdrawn.

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CONCLUSION

For all of the foregoing reasons, Applicant traverses the restriction requirements.

Respectfully submitted,

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